§419.45 Payment and copayment reduction for devices replaced without cost or full credit is received.

(a) *General rule.* CMS reduces the amount of payment for an implanted device made under the hospital outpatient prospective payment system in accordance with §419.66 for which CMS determines that a significant portion of the payment is attributable to the cost of an implanted device, when one of the following situations occur:

(1) The device is replaced without cost to the provider or the beneficiary; or

(2) The provider receives full credit for the cost of a replaced device.

(b) *Amount of reduction to the APC payment.* The amount of the reduction to the APC payment made under paragraph (a) of this section is calculated in the same manner as the offset amount that would be applied if the device implanted in a procedure assigned to the APC had transitional pass-through status under §419.66.

(c) *Amount of beneficiary copayment.* The beneficiary copayment is calculated based on the APC payment after application of the reduction under paragraph (b) of this section.

[71 FR 68228, Nov. 24, 2006]

Subpart E—Updates

§419.50 Annual review.

(a) *General rule.* Not less often than annually, CMS reviews and updates groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

(b) *Consultation requirement.* CMS will consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise CMS concerning) the clinical integrity of the groups and weights. The panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting the review.

(c) *Effective dates.* CMS conducts the first annual review under paragraph (a) of this section in 2001 for payments made in 2002.

Subpart F—Limitations on Review

§419.60 Limitations on administrative and judicial review.

There can be no administrative or judicial review under sections 1869 and 1878 of the Act or otherwise of the following:

(a) The development of the APC system, including—

(1) Establishment of the groups and relative payment weights;

(2) Wage adjustment factors;

(3) Other adjustments; and

(4) Methods for controlling unnecessary increases in volume.

(b) The calculation of base amounts described in section 1833(t)(3) of the Act.

(c) Periodic adjustments described in section 1833(t)(9) of the Act.

(d) The establishment of a separate conversion factor for hospitals described in section 1886(d)(1)(B)(v) of the Act.

(e) The determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under §419.43(d) or the determination of insignificance of cost, the duration of the additional payments (consistent with subpart G of this part), the determination of initial and new categories under §419.66, the portion of the Medicare hospital outpatient fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under §419.62(c).

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 55856, Nov. 2, 2001]

Subpart G—Transitional Pass-through Payments

SOURCE: 66 FR 55856, Nov. 2, 2001, unless otherwise noted.

§419.62 Transitional pass-through payments: General rules.

(a) *General.* CMS provides for additional payments under §§419.64 and 419.66 for certain innovative medical devices, drugs, and biologicals.